SUCTION CONTROLLED EXTRACTION DEVICE

CROSS-REFERENCE TO RELATED APPLICATION

[0001] This application claims the benefit of U. S. Provisional Application Serial No. 60 / 373,231, filed April 17, 2002, the disclosure of which is hereby incorporated by reference.

BACKGROUND OF THE INVENTION

1. Field of the Invention:

[0002] The present invention pertains to medical devices. More particularly, the present invention concerns devices for extracting foreign objects from a body cavity or canal. Even more particularly, the present invention concerns suction devices for removing foreign bodies from the auditory canal or endonasal cavity or passage.

2. Description of Prior Art:

[0003] Foreign bodies located in the external auditory canal as well as the endonasal cavity continue to present unique challenges for the treating physician or other medical personnel. Reported incidences vary, but account for roughly 1/500 pediatric and 1/1500 adult attendances. Endaural occurrences tend to outnumber endonasal occurrences, and a preponderance of both occurs in male children of lower socioeconomic status. The challenge in management of this largely younger target population is to be able to provide reliable, single attempt, atraumatic extraction and avoid the need for general anesthesia, which can occur

in 8-10% of cases. Inadequate visualization and access, inappropriately sized instruments, poor patient cooperation, multiple prior attempts with secondary inflammatory reaction, impaction, inexperience, and foreign body consistency and location have been cited as causes for treatment failures.

[0004] The three standard methods of foreign body removal include direct instrumentation (ear, nose), irrigation (ear), and suction (ear, nose). Complications have been reported when using direct instrumentation. These complications include cutaneous or mucosal excoriation, abrasion, laceration; bleeding, canal hematoma, otitis externa, facial nerve palsy, iatrogenic tympanic membrane perforation, and aspiration of the foreign body. Direct instrumentation (e.g., Hartman or alligator forceps) can be successfully used for soft objects that present a leading edge or harder, larger objects that will allow placement of a hook or wire loop behind it. For those foreign bodies that are spherical, impacted by occlusion, or lying against the tympanic membrane, such attempts at manipulation can be difficult if not impossible, and potentially dangerous to the patent.

[0005] Irrigation affords a relatively atraumatic means for foreign body extraction in the ear canal, particularly in children, but is generally contraindicated with existent tympanic membrane perforations, monomeric tympanic membranes, presence of grommets (relative), hydroscopic or metallic foreign bodies (especially button batteries), and vegetable matter. Additionally, a totally impacted foreign body precludes the beneficial backwash effect of the

irrigation solution from dislodging it.

[0006] Several techniques for the less traumatic suction extraction of foreign bodies have been described by modifying the end of IV tubing or by affixing a beveled tympanostomy tube within a Frazier suction cannula. While successful in certain cases, they are crude in construction, fail to provide illumination or magnification, and present a limited, non-conformable contact interface.

[0007] Other less traditional methodologies have also been reported, e.g., cyanoacrylate contact adhesion, foreign body embedment, and balloon catheter extraction, with similar deficiencies and restrictive applications.

[0008] The present invention, as detailed hereinafter, provides a universal instrument that efficiently enables extraction of a foreign object from a body cavity or canal, especially the auditory canal and the endonasal cavity or passage.

BRIEF DESCRIPTION OF THE DRAWINGS

[0009] FIGURE 1 is an exploded, perspective view of the extraction device of the present invention; and

[00010] FIGURE 2 is a view of a suction regulator used herein.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

[00011] In accordance with the present invention, and as noted hereinabove, there is provided an extraction device or extractor for removing foreign objects from an external auditory canal, endonasal cavity, or other body passages or cavities where foreign objects can be lodged.

[00012] Turning now to the drawings, there is shown in FIG. 1 a preferred embodiment of the extraction device, generally denoted at 10. The extraction device 10 comprises an elongated hollow tubular structure (or suction tube) 12 that is connected to a vacuum or other source of suction (i.e., a source which produces a negative pressure of sufficient magnitude to draw the foreign object against an insertion end of the tube structure), and means 17 for varying or controlling the degree of suction in the tubular structure 12.

[00013] The tubular structure 12 includes a first portion 14 and a second portion 16, each portion being elongated, hollow, and generally circular in cross-section. Preferably, each tubular portion 14 and 16 is formed from a non-toxic material, such as a silicone or the like.

[00014] The first portion 14 includes a distal end 20, a central body portion 30, and a proximal end 21. Preferably, the opposite ends 20 and 21 of the first portion 14 are frusto-conically shaped (i.e., flare outwardly and increase in diameter) relative to the central body portion 30. The distal end 20 of the first portion 14 is placed within the ear or nose cavity and dimension so as to be in enveloping juxtaposition with the foreign object. The proximal end 21 is

removably connected to the means 17 for varying or controlling the degree of suction.

[00015] The first portion 14 is curvilinear relative to the central body portion 30. As such, the distal end 20 is in an angular relation with the proximal end 21.

[00016] Preferably, the opposite ends 20 and 21 of the first portion 14 are offset and at an angle Θ of about 100° to about 150° to one another. More preferably, the angular offset Θ is about 130° to about 140°.

[00017] Further, the first portion 14 is formed from a hard, rigid, non-toxic material, such as silicone, rubber, or the like.

[00018] According to an important aspect of this invention, an enveloping lip 22 is removably mounted to the distal end 20 by any suitable means, such as a slip fit or the like. The lip 22 is an annular or toroidal structure that envelops the foreign object (not shown). The lip 22 is preferably formed from a flexible, non-toxic material, such as a silicone rubber, which can be placed over the foreign object. Preferably, frusto-conical lips of different diameter may be mounted to the distal end of the first portion. That is, a lip 22 of predetermined size may be selected for fitment to the distal end of the first portion 14 wherein to accommodate the foreign object, as needed and depending on the patient. So fitted, the distal end 20 of the first portion 14 and the lip 22 fitted thereto form a smooth, continuous, frusto-conical insertion tip.

[00019] Also, and according to an aspect of this invention, the lip 22 can be integrally formed with the first portion 14. Under such circumstances, the user would be provided with a plurality of tubular sections, each section being integrally formed with a lip of different diameter.

[00020] Referring again to FIG. 1, the second portion 16 of the tubular structure 12 has a distal end 24 operatively connected to the means 17 for varying or controlling the suction pressure, and a proximal end 26 adapted to be removably connected to the source of suction, such as a vacuum or the like (not shown).

[00021] As shown in FIG. 1, preferably, the outer surface of the second portion 16 is convoluted at 28. This convolution extends along a section of the second portion 16 and enables easy and secure gripping by virtue of its rubber-like construct.

[00022] Preferably, the second portion 16 of the tubular structure 12 is formed from a suitable non-toxic material, such as a rubber, silicone, or the like.

[00023] The means 17 for varying or controlling the suction pressure is preferably interposed between the proximal end 21 of the first portion 14 and the distal end 24 of the second portion 16 and enables air to be drawn between the first and second portion 14 and 16.

[00024] In a first embodiment thereof, and referring more particularly to FIG. 2, the means 17 for varying and controlling vacuum pressure comprises, in part, a coupler 32. The coupler 32 includes a housing body 44 having opposite

ends 34 and 36, and a Venturi passage 38 therethrough, the ends 34 and 36 forming an inlet and outlet to the passage 38. The inlet end 34 is capable of engaging and completing a fluid connection to the proximal end 21 of the first portion 14, such as through a slidable mounting or the like. The outlet end 36 is capable of engaging and completing a fluid connection to the distal end 24 of the second portion 16.

[00025] The Venturi passage 38 has a restricted throat 40, in a conventional manner. A valve 42, located within the housing body 44, regulates the degree of opening of the Venturi passage 38 at the restricted throat 40. The valve 42 is in the form of a stem, disposed for rotation in the passage 38, and provided with a central passage 48. The valve 42 functions in a manner similar to a stopcock and the central passage 48 operates to complete a fluid connection between the Venturi passage 38 and the internal passages of the tubular portions 14 and 16.

[00026] In a first position, the central passage 48 of the valve stem 42 is in register with the Venturi passage 38, representing a fully open condition. In a second position, the valve stem 42 is rotated 90°, and the central passage 48 of the stem 42 is rotated out of register with the Venturi passage 38, representing a fully closed position wherein the suction source cannot draw the foreign object into and against the insertion lip 22. The amount of rotation of the stem 42 between these two extremes provides a predetermined degree of passage openness between the fully open and fully closed positions and suction force available.

[00027] Means 46 for controlling movement of the valve, such as dial 48, is operatively connected to the valve 42.

[00028] It is also possible to position the means for controlling suction proximate to the vacuum source.

[00029] Also, the housing body 44 can be integral with the tubular structure 12 and configured to house the stopcock valve 42. In this manner, the tubular structure 12 can be assembled as a unitary structure.

[00030] A magnifying lens 50, or the like, can be affixed to the first portion 14 to enable the user, such as a physician, to see within the canal or cavity, to ensure that the lip 22 envelops the foreign object to be removed.

[00031] In operation, the forward insertion tip or enveloping lip 22 of the extraction device 10 is inserted into the canal or cavity with the lip 22 engaging the foreign object. Thereafter, the suction is applied; the degree of suction being controlled through the means 17 for controlling. As suction is applied, the foreign object is drawn against the enveloping lip 22 and is safely removed.

[00032] The present invention provides numerous beneficial features, amongst which are the following:

1. Universal Application – can be used in the ear canal and nasal cavity irrespective of tympanic membrane status, foreign body shape, size or location.

2. Simplicity – prefabricated, handheld instrument requires only visualization of foreign body, tip contact, and vacuum extraction.

3. Adaptability – selection of interchangeable suction heads and control over vacuum pressures optimizes extraction suction with varying foreign body shapes, sizes, and degrees of impaction.

4. Magnification – afforded by suction tube mounted magnifying lens.

5. Patient tolerance – least potentially traumatic method of extraction since foreign body only is engaged rather than manipulated.

6. Cost effective – a single avoidance of intraoperative anesthesia for foreign body removal covers purchase cost twenty-fold.

[00033] The present invention provides an efficient and effective means for removing foreign objects from body cavities and canals.

[00034] While the present invention has been described with respect to specific embodiments, it will be understood that from the foregoing detailed description and accompanying drawings that various modifications and variations will occur to those skilled in the art. Such modifications and variations are intended to fall within the scope of the appended claims.